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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MARX, IRENE	
ART UNIT	PAPER NUMBER
1651	18

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/787,893	Applicant(s) Naruszewicz
	Examiner Irene Marx	Art Unit 1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Dec 19, 2002* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *11 and 15-40* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *11 and 15-40* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

The application should be reviewed for errors. Error occurs, for example, in the recitation "is administered is administered" in claim 27.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 19, 2002 has been entered.

Claims 11 and 15-40 are being considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 23 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for the designation of cancer as an inflammatory disease. Cancer is only mentioned in the as-filed specification in the context that "with chronic inflammation there is a risk of an increased ageing process, atherosclerosis and cancer" (page 1, paragraph 5). This statement cannot be equated with cancer being an inflammatory disease.

Therefore, this material raises the issue of new matter and should be deleted.

In response the applicant's extensive arguments regarding applicant's right as a lexicographer, it is submitted that cancer was never indicated as an inflammatory disease on the present record. (Response, page 7 et seq.)

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11 and 15-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11 and 28 are vague, indefinite and confusing in the recitation of "reducing the levels of at least one oxidative stress factor in the blood of a mammal". The "reduction" intended cannot be readily ascertained, since the dosage and protocol of administration are not indicated. Also, it is not clear whether the bacteria administered are alive or dead.

Claims 11, 24 and 31 are confusing in the recitation "in need thereof of *Lactobacillus...*". It is unclear what intended in this context.

Claims 18-19 are vague and indefinite in that the claims fails to specify the dosage and protocol of administration of "effective amounts" of gruel. Inasmuch as the content, protocol of administration and viability of *L. plantarum* are not claim designated, it is unclear how the amount of gruel is to be determined, particularly since "at least one oxidative stress factor is involved", a concept which is not clearly defined as to what is intended, even when reading the claims in light of the specification. The amount intended cannot be ascertained. Similarly, claim 20 is vague and indefinite in the recitation "is administered.... for a time period ranging from 3 to 6 weeks". The claim fails to specify the dosage and protocol of administration in the designated time period.

Claims 21, 28 and 35, are vague and indefinite since it is not indicated whether the "heavy smoker" smokes cigarettes, cigars, pipes, marihuana, etc. Also it is unclear how the level of "heavy" with regard to smoking is to be assessed in order to properly identify the mammal in need of administration of the claim designated invention. Is it 10, 20, 30, 40 or more cigarettes or cigars an hour, a day or a week? No clear definitions or identification of the subjects tested are provided in the as filed specification.

Claims 24 and 39 are vague, indefinite and confusing in the recitation of "increasing the levels of fecal concentration of propionic acid in a mammal". The "increase" intended cannot be readily ascertained, since the dosage and protocol of administration are not indicated. Also, it is not clear whether the bacteria administered are alive or dead.

Claims 31 and 40 are vague indefinite and confusing in that the amount of "reduction" intended cannot be readily ascertained or how the "reduction" is assessed in every endothelial, since the dosage and protocol of administration are not indicated. Also, it is not clear whether the bacteria administered are alive or dead.

When a word of degree, such as "increasing" or "reducing" is used as a limitation, it is necessary to determine whether the specification provides some standard for measuring that degree. See *Seattle Box Company, Inc. V. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984). In this case, the specification does not enable one skilled in the art to reasonably establish what may be construed as being within the metes and bounds of the word of degree. Therefore, one of ordinary skill in the art would not be apprised as to the claimed invention's scope when the claims are read in light of the specification. See *Ex parte Oetiker*, 23 USPQ2d 1641.

Claims 38-40 are vague, indefinite and confusing in that it is unclear whether 25 ml of gruel is the total amount provided in 6 weeks or whether it is provided every hour on the hour, once a day, twice a day, once a week, etc.. Also the dosage and protocol of administration of the active ingredient, i.e., of live bacteria provided in the at least 25 ml of gruel are not defined with any particularity.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant's contention that patents are issued all the time without an indication of baseline, timing and dosage requirements is noted. Applicant's citation of previously granted patents is not persuasive regarding the prosecution of the present application, since each patent application is prosecuted on its own merits and what was done in a previous case does not

constitute imprimatur for the prosecution of further cases. In the patent '428 the issues and content of the specification are materially different, even though the term "reducing" is recited in the claims regarding "lactose intolerance". Applicant fails to note that the methods in '428 pertain to the use of a composition having a specific, claim designated concentration of viable *Lactobacillus acidophilus,* yeast and protein and that appropriate dosages are recited in the specification.

Applicant failed to address the rejection regarding the nature and definition of the smoker intended.

Therefore the rejection is deemed proper and it is adhered to.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11, 15-18, 22-25, 29, 31-32, and 36-37 are/remain rejected under 35 U.S.C. 102(b) as being anticipated by Bengmark et al. (5,587,314) for the reasons as stated in the last Office action and the further reasons below.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant's contention that Bengmark only demonstrates that *L. plantarum* 299v may be cultured in the stomach of mammals is incorrect. The reference discloses the administration of *L. plantarum* 299v to humans. See, e.g., Table 1, wherein 299v is reported as A1. Applicant argues that a mammal population has to be identified to "select" a mammalian population in need. However, as indicated previously, no selection is required for the process of the instant invention inasmuch as all mammals are "in need" of reduction of oxidative stress factors in blood, of increase levels of fecal concentration of propionic acid and of reduction of adhesion of monocytes to endothelial cells, to ameliorate the ravages of ageing, for example. Moreover, the

inherent properties of the composition administered, i.e. of *L. plantarum* 299v, are invariant and kick in upon administration of the microbe to the individual, whether all of the effects and properties are known or not. In the instant the same microorganism is administered to the same patient. Therefore the effects are surely the same. Contrary to the contentions presented, Applicant is **not** claiming a new process of use of an old composition. Applicant is claiming a process of use which is not novel, since it reads on the process taught in the Bengmark *et al.* reference. The subjects therein are administered the same *L. plantarum* 299v strain and likewise are in need of reduction of oxidative stress factors in blood, of increase levels of fecal concentration of propionic acid and of reduction of adhesion of monocytes to endothelial cells, as indicated previously. Inasmuch as inflammation and atherosclerosis are conditions that are prevalent in most, if not all, humans, at least to some extent, it can reasonably be presumed that at least one of the subjects to whom the medicament containing *L. plantarum* 299v was administered suffered from at least one symptom of inflammatory disease and/or from atherosclerosis at least to some extent at the time of testing.

It is emphasized that whenever the active step of the method is the same and the subject is the same, then the claimed method can be anticipated or made obvious by the prior art, even if the prior art does not recognize or appreciate the mechanism as long as the compound administered, dosage, mode of administration, subject, etc. are the same as in the method disclosed in the prior art. In the instant case the identical strain is administered to the same subjects by the same mode of administration. The amount provided is not at issue, since the dosage and protocol of administration are not claim designated.

In the instant case, the "reducing the levels of at least one oxidative stress factor in the blood of a mammal"; "increasing the levels of fecal concentration of propionic acid in a mammal" and/or "reducing the adhesion of monocytes to endothelial in a mammal" flows from the administration of *L. plantarum* 299v to humans, who are mammals in need of a treatment that ameliorates the effects of ageing. Thus applicants are incorrect in arguing that the anticipatory rejection is improper.

Applicant argues that the case law is directed to compositions. However, at least in *Ex parte Novitski*, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993) the board rejected a claim directed to a method for protecting a plant from plant pathogenic nematodes by inoculating the plant with a nematode inhibiting strain of *P. cepacia*. A US patent to Dart disclosed inoculation using *P. cepacia* bacteria for protecting the plant from fungal disease. Dart was silent with regard to nematode inhibition, but the Board **concluded that nematode inhibition was an inherent property of the bacteria, and therefore of the method as disclosed by Dart.**

As noted in the last Office action, Rapoport can be distinguished over the instant case in that in that decision there is a clear difference in the **timing** of administration of the medicament and the **purpose** of administration, which is for a **specific** ailment, i.e., sleep apnea. This cannot reasonably be equated with the claimed processes herein, having no particular requirements or disclosure relating to dose to be administered and wherein the processes are directed to broad and undefined effects, such as "reduction of levels of oxidative stress factors in blood" "increase in the fecal concentration of propionic acid" and "reduction of the adhesion of monocytes to endothelial cells". There is not even an requirement that the microorganism administered be "viable".

The absence of specific dosages, administration protocol, timing of administration and the sweeping and all-encompassing the nature of the intended "oxidative stress factors in blood" and the increases and reductions intended precludes arguments that the intended effects are "specific" in nature, as in Rapoport, or that administration for any purpose to the same subject, would not meet the broad recitations in the claims.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone

number for the organization where this application or proceeding is assigned is before final (703) 872-9306 and after final, (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.

Irene Marx
Primary Examiner
Art Unit 1651